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August 23, 2000

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Office of Special Nutritionals (HFS-450)  
Center for Food Safety & Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, D.C. 20204

*Received*  
AUG 29 2000

Dear Sir or Madam:

This letter will serve as 30-day notification, pursuant to section 403 (r)(6) of the Federal Food, Drug & Cosmetic Act and regulations promulgated thereunder.

Name and address of Dietary Supplement Manufacturer: Twin Laboratories, Inc.  
150 Motor Parkway  
Hauppauge, NY 11788

Text of statement being made: "Creatine plays an important role in the transfer of energy. In the muscle, it is used to fuel the process of contraction. It is converted to phosphocreatine which is important for short energy bursts such as sprinting and weightlifting. Depletion of phosphocreatine can result in muscular fatigue and fading muscle power. By combining creatine monohydrate with creatine pyruvate plus phosphates and ATP you can: Improve the resynthesis of creatine phosphate and ATP over creatine alone, providing you with more energy and quicker recovery that help athletes get bigger and stronger faster; Reduce the build-up of lactic acid; Increase max  $\text{Vo}_2$  and oxygen delivery to the muscles for more powerful workouts; Reduce onset of muscular fatigue so you can train longer and harder. This revolutionary supplement takes creatine supplements to new levels of strength, power and stamina."

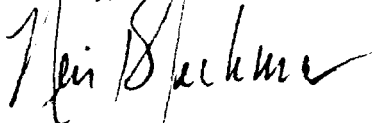
Dietary supplement ingredients: Creatine Monohydrate and Creatine Pyruvate, Potassium Phosphate and ATP (Adenosine Triphosphate).

Dietary supplement brand and name: Twinlab Ironman ADVANCED CREATINE.

As required, enclosed are two photocopies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Twin Laboratories, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,



Neil Blechman  
Executive Vice President  
Twin Laboratories, Inc.

975-0162  
Enclosures

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